

Adopted	Rejected
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## COMMITTEE REPORT

YES:	10
NO:	0

### MR. SPEAKER:

*Your Committee on Public Health, to which was referred House Bill 1458, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill **be amended** as follows:*

- 1 Delete the title and insert the following:
- 2 A BILL FOR AN ACT to amend the Indiana Code concerning
- 3 Medicaid.
- 4 Page 1, between the enacting clause and line 1, begin a new
- 5 paragraph and insert:
- 6 "SECTION 1. IC 12-15-35-28, AS AMENDED BY P.L.107-2002,
- 7 SECTION 17, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
- 8 JULY 1, 2003]: Sec. 28. (a) The board has the following duties:
- 9 (1) The adoption of rules to carry out this chapter, in accordance
- 10 with the provisions of IC 4-22-2 and subject to any office
- 11 approval that is required by the federal Omnibus Budget
- 12 Reconciliation Act of 1990 under Public Law 101-508 and its
- 13 implementing regulations.
- 14 (2) The implementation of a Medicaid retrospective and
- 15 prospective DUR program as outlined in this chapter, including
- 16 the approval of software programs to be used by the pharmacist

1 for prospective DUR and recommendations concerning the  
2 provisions of the contractual agreement between the state and any  
3 other entity that will be processing and reviewing Medicaid drug  
4 claims and profiles for the DUR program under this chapter.

5 (3) The development and application of the predetermined criteria  
6 and standards for appropriate prescribing to be used in  
7 retrospective and prospective DUR to ensure that such criteria  
8 and standards for appropriate prescribing are based on the  
9 compendia and developed with professional input with provisions  
10 for timely revisions and assessments as necessary.

11 (4) The development, selection, application, and assessment of  
12 interventions for physicians, pharmacists, and patients that are  
13 educational and not punitive in nature.

14 (5) The publication of an annual report that must be subject to  
15 public comment before issuance to the federal Department of  
16 Health and Human Services and to the Indiana legislative council  
17 by December 1 of each year.

18 (6) The development of a working agreement for the board to  
19 clarify the areas of responsibility with related boards or agencies,  
20 including the following:

21 (A) The Indiana board of pharmacy.

22 (B) The medical licensing board of Indiana.

23 (C) The SURS staff.

24 (7) The establishment of a grievance and appeals process for  
25 physicians or pharmacists under this chapter.

26 (8) The publication and dissemination of educational information  
27 to physicians and pharmacists regarding the board and the DUR  
28 program, including information on the following:

29 (A) Identifying and reducing the frequency of patterns of  
30 fraud, abuse, gross overuse, or inappropriate or medically  
31 unnecessary care among physicians, pharmacists, and  
32 recipients.

33 (B) Potential or actual severe or adverse reactions to drugs.

34 (C) Therapeutic appropriateness.

35 (D) Overutilization or underutilization.

36 (E) Appropriate use of generic drugs.

37 (F) Therapeutic duplication.

38 (G) Drug-disease contraindications.

- 1 (H) Drug-drug interactions.
- 2 (I) Incorrect drug dosage and duration of drug treatment.
- 3 (J) Drug allergy interactions.
- 4 (K) Clinical abuse and misuse.
- 5 (9) The adoption and implementation of procedures designed to
- 6 ensure the confidentiality of any information collected, stored,
- 7 retrieved, assessed, or analyzed by the board, staff to the board, or
- 8 contractors to the DUR program that identifies individual
- 9 physicians, pharmacists, or recipients.
- 10 (10) The implementation of additional drug utilization review
- 11 with respect to drugs dispensed to residents of nursing facilities
- 12 shall not be required if the nursing facility is in compliance with
- 13 the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR
- 14 483.60.
- 15 (11) The research, development, and approval of a preferred drug
- 16 list for:
  - 17 (A) Medicaid's fee for service program;
  - 18 (B) Medicaid's primary care case management program; and
  - 19 (C) the primary care case management component of the
  - 20 children's health insurance program under IC 12-17.6;
  - 21 in consultation with the therapeutics committee.
- 22 (12) The approval of the review and maintenance of the preferred
- 23 drug list at least two (2) times per year.
- 24 (13) The preparation and submission of a report concerning the
- 25 preferred drug list at least two (2) times per year to the select joint
- 26 commission on Medicaid oversight established by IC 2-5-26-3.
- 27 (14) The collection of data reflecting prescribing patterns related
- 28 to treatment of children diagnosed with attention deficit disorder
- 29 or attention deficit hyperactivity disorder.
- 30 (b) The board shall use the clinical expertise of the therapeutics
- 31 committee in developing a preferred drug list. The board shall also
- 32 consider expert testimony in the development of a preferred drug list.
- 33 (c) In researching and developing a preferred drug list under
- 34 subsection (a)(11), the board shall do the following:
  - 35 (1) Use literature abstracting technology.
  - 36 (2) Use commonly accepted guidance principles of disease
  - 37 management.
  - 38 (3) Develop therapeutic classifications for the preferred drug list.

(4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that ~~is not included on~~ **has been excluded from** the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date **on which the manufacturer notifies the board in writing** of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be ~~automatically~~ required for a single source drug that is newly approved by the federal Food and Drug Administration, ~~and that is:~~

~~(1) in a therapeutic classification:~~

~~(A) that has not been reviewed by the board; and~~

~~(B) for which prior authorization is not required; or~~

~~(2) the sole drug in a new therapeutic classification that has not been reviewed by the board.~~

**pending a determination by the board under this chapter.**

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list developed under subsection (a)(11):

(1) **Except as provided by IC 12-15-35.5-3(b)**, the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

(A) To override a prospective drug utilization review alert.

(B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.

(C) To prevent fraud, abuse, waste, overutilization, or

1 inappropriate utilization.

2 (D) To permit implementation of a disease management  
3 program.

4 (E) To implement other initiatives permitted by state or federal  
5 law.

6 (2) All drugs described in IC 12-15-35.5-3(b) must be included on  
7 the preferred drug list.

8 (3) The office may add a ~~new single source~~ drug that has been  
9 approved by the federal Food and Drug Administration to the  
10 preferred drug list without prior approval from the board.

11 (4) The board may add a ~~new single source~~ drug that has been  
12 approved by the federal Food and Drug Administration to the  
13 preferred drug list.

14 (h) At least two (2) times each year, the board shall provide a report  
15 to the select joint commission on Medicaid oversight established by  
16 IC 2-5-26-3. The report must contain the following information:

17 (1) The cost of administering the preferred drug list.

18 (2) Any increase in Medicaid physician, laboratory, or hospital  
19 costs or in other state funded programs as a result of the preferred  
20 drug list.

21 (3) The impact of the preferred drug list on the ability of a  
22 Medicaid recipient to obtain prescription drugs.

23 (4) The number of times prior authorization was requested, and  
24 the number of times prior authorization was:

25 (A) approved; and

26 (B) disapproved.

27 (i) The board shall provide the first report required under subsection  
28 (h) not later than six (6) months after the board submits an initial  
29 preferred drug list to the office.

30 SECTION 2. IC 12-15-35-28.7, AS ADDED BY P.L.107-2002,  
31 SECTION 19, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
32 JULY 1, 2003]: Sec. 28.7. (a) The board shall submit the initial  
33 approved preferred drug list to the office not later than August 1, 2002.

34 (b) Except as permitted under subsection (g), the office may not  
35 further restrict the status of a drug in the Medicaid program or the  
36 children's health insurance program until the board reviews a  
37 therapeutic classification and the office implements the therapeutic  
38 classification on the preferred drug list.

(c) The office shall provide advance notice to providers of the contents of the preferred drug list submitted by the board under subsection (a).

(d) Notwithstanding IC 12-15-13-6, the office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.

(e) **Except as provided by section 28(g)(3) of this chapter**, the office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.

(f) The office may not require prior authorization for a drug that is excluded from the preferred drug list unless the board has made the determinations required under section 35 of this chapter.

(g) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter.

SECTION 3. IC 12-15-35-43.5, AS ADDED BY P.L.107-2002, SECTION 21, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 43.5. (a) The board, the therapeutics committee, or the office may not release proprietary or confidential information obtained as part of the development, implementation, or maintenance of a preferred drug list under this chapter.

(b) **Information described in subsection (a) is confidential for purposes of IC 5-14-3-4(a)(1).**

SECTION 4. IC 12-15-35.5-2.5, AS ADDED BY P.L.107-2002, SECTION 23, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 2.5. As used in this chapter, "unrestricted access" means the ability of a recipient to obtain a prescribed drug without being subject to limits or preferences imposed by the office or the board for the purpose of cost savings except **to address situations described in IC 12-15-35-28(a)(8)(A) through (K) and** as provided under ~~IC 12-15-35-8~~ and section 7 of this chapter."

Page 2, line 5, after "act;" insert "**and**".

Page 2, line 11, delete "; and" and insert ".".

- 1 Page 2, delete lines 12 through 13.
- 2 Renumber all SECTIONS consecutively.  
(Reference is to HB 1458 as introduced.)

**and when so amended that said bill do pass.**

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Representative Brown C